

REMARKS

Applicant has amended claim 1 for clarification purposes. No new matter has been added. Support is found, for example, in paragraph [0083] among others of the specification.

On page 2 of the Office Action, claims 1, 2 and 4-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armato et al., U.S. Patent No. 7,285,637 (“Armato”), and if necessary in view of Li et al., U.S. Patent No. 6,303,136 (“Li”) and Takezawa et al., U.S. Patent No. 5,736,399 (“Takezawa”). Applicant submits that Armato teaches away from the present invention and, therefore, is not properly combinable with Li and Takezawa to render the present invention obvious for the reasons set forth below. Applicant submits herewith as support for its position a Declaration under 37 C.F.R. § 1.132 of inventor Gregory H. Altman, Ph.D.

As stated in his Declaration, Dr. Altman has extensive experience in the field of silk medical devices including implantable knitted silk fabrics. Dr. Altman states, “In my opinion, a person of ordinary skill in the art would not consider the claimed invention in this patent application to be obvious based upon Armato or Armato in combination with either of the two other cited references.” Dr. Altman states that he bases his opinion on facts including that “Armato is directed to a process for producing non-woven silk fiber fabrics, as stated in the title and abstract of Armato.” Dr. Altman further states that he bases his opinion on the fact that “Armato’s fibers are randomly organized whereas the fibers of our invention are non-randomly organized.” Thus, Armato teaches away from the “non-randomly organized fibers” in the fabric of the present invention. The Examiner relies in the Office Action on the statement in Armato that “[t]he use of textile methods would theoretically be possible to weave using merely degummed silk fibroin fibers in order to obtain a flexible fabric.” But, Armato in the very next sentence further qualifies this statement by stating that “[h]owever, preparing three dimensional structures appears to be remarkably difficult, and the adaptability of a tissue obtained in such a way would not be entirely proper to the different applicative requirements in terms of specifically required mechanical attributes, structure, and even ability to interact with other cells.” Thus, in light of the above, Armato specifically states in col. 2, lines 32-33 that “[t]he aim of the present invention is to provide a method for the preparation of silk fibroin *non-woven* fabrics...” (emphasis added). Applicant submits that it is well-known to one of ordinary skill in the art that non-woven fabrics are randomly organized.

Dr. Altman also states that among the facts upon which he bases his opinion “Figures 1A and 1B of Armato are scanning electron microscopy (SEM) pictures of non-woven fabrics.” Furthermore, Figures 1A and 1B of Armato clearly set forth SEM pictures of silk fibroin fabrics made up by the non-woven meshwork of fibers and fibrils randomly bonded together (see also col. 3, lines 22-24 of Armato) in accordance with Armato’s teachings. Armato specifically states in col. 5, lines 58-62 that “It can be clearly noted in SEM photographs that voids are distributed randomly and can be controlled by the concentration of silk fibroin or by preparing multiple layers of silk fibroin fiber structures.” Thus, the teachings of Armato are contrary to Applicant’s claimed invention.

Dr. Altman indicates that he bases his opinion on the fact that “[n]on-woven fabrics (Armato) are different from knitted fabrics both in terms of the structural construction of the fabrics and the configuration of the fibers.” The Declaration of Dr. Altman sets forth technical support in the literature for the distinctions between the fabric types of: woven, knitted and nonwoven. Dr. Altman points out that “Armato clearly teaches only a process for producing ‘non-woven’ silk fiber fabrics which is contrary to the teachings of our claimed invention...” He further states “In contrast, our knitted implantable fabric is comprised of non-randomly organized fibers as set forth in our claims. And as stated Li discloses that the matrix is ‘woven’ into a mesh (see abstract of Li) and Takezawa discloses a device comprising ‘the woven body thereof’ (column 2, line 25). With regard to Li, Applicant reemphasizes that the filamentous matrix of Li formed of silk is a non-degradable silk suture matrix, which is unsuitable for the present invention. Applicant submits that Li teaches a silk that is unsuitable for use in the fabric of the present invention and such teaching cannot be disregarded, as the suitability of the silk is important to its use as an implantable fabric and not just a cell culture carrier. Applicant submits that the teachings of Takezawa are even further removed from the presently claimed invention.

Dr. Altman also states in his Declaration that “Furthermore, it is clear that the fibers of Armato have been dissolved and reconstituted as shown in the Examples of Armato (see column 4, lines 50-52 of Armato).” The process of Armato requires degumming and explicitly states that “[s]uch treatment is favourably performed partially dissolving the silk fibroin in a formic acid solution.” Once again, Armato explicitly teaches away from the invention and is contrary to Applicant’s claimed invention which claims “sericin-extracted silk fibroin fibers that retain their

native protein structure and have not been dissolved and reconstituted.” Armato is very clear on its face that the fibers have been dissolved and reconstituted. As stated in col. 4, lines 50-52 of Armato, “the process in accordance with the present invention allows the silk fibroin to be dissolved.”

Thus, Applicant submits that it is improper for the Examiner to selectively rely upon certain teachings in a cited reference but not others in order to render the present invention obvious, alone or in combination with the other cited references. The Examiner must take the teachings of each reference as a whole. Thus, the present invention as claimed cannot be rendered obvious given *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984), which held that a prior art reference must be considered in its entirety, including those portions that would lead away from the claimed invention. In view of the above, Applicant respectfully requests reconsideration and withdrawal of the rejection.

In view of the foregoing, it is respectfully urged that the present claims, as amended, are in condition for allowance and reconsideration is requested. An early notice to this effect is earnestly solicited. Should there be any questions regarding this application, the Examiner is invited to contact the undersigned at the number shown below.

Please use Deposit Account 01-0885 for the payment of any extension of time fees, and/or the payment of any other fees due in connection with the present response.

Dated: May 10, 2012

Respectfully submitted,

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